

Remarks

Claims 75-103 are pending in the subject application. Applicants acknowledge that claims 104-124 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have amended claims 75, 78, 79, 81, 82, 85, 86, 88, 89, 92, 93, 95, 96, 99, 100, 102, 104, 107, 108, 110, 116, 117, 119, 123 and 124 and added new claims 125-140. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 75-140 are currently before the Examiner (with claims 104-124 standing withdrawn from consideration). Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication that claims 76, 77, 80, 83, 84, 87, 90, 91 and 94 are objected to but would be allowable if rewritten into independent form to include the limitations of any base and intervening claims.

As the Examiner is aware, this application is a national stage application and is subject to the unity of invention rules for restriction. The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept. The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. Additionally, a group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. In this case, it is respectfully submitted that the amended claims are novel and non-obvious over the cited prior art in this matter and those claims that were withdrawn from consideration have been amended in a manner similar to the claims under examination. Accordingly,

rejoinder of the non-elected claims with the examined claims is respectfully requested as all of the claimed inventions should be considered as being linked to form a single general inventive concept. Accordingly, rejoinder of the withdrawn inventions (drawn to isolated polynucleotides, vectors and transformed host cells) is respectfully requested.

The application is objected to on the grounds that the subject specification fails to comply with the requirements of 37 CFR 1.821-1.825. Specifically, the Examiner indicates that Figures 1, 3-8, 10, 11 and 13 contain amino acid and nucleotide sequences that are not identified by a SEQ ID NO.: Applicants note that section 2422.02 of the M.P.E.P. indicates that:

In view of the fact that many significant sequence characteristics may only be demonstrated by a figure, the exclusive conformance requirement of this section may be relaxed for drawing figures. This is especially true in view of the fact that the representation of double stranded nucleotides is not permitted in the "Sequence Listing" and many significant nucleotide features, such as "sticky ends" and the like, will only be shown effectively by reference to a drawing figure. Further, the similarity or homology between/among sequences can only be depicted in an effective manner in a drawing figure.

In light of this guidance, Applicants note that the alignment presented in the line between the Query and Subject lines in Figures 1, 8 and 11 represents the depiction of the alignment result and that the sequence rules do not provide for an adequate means of presenting such a sequence in a sequence listing. As stated in section 2423.03 of the M.P.E.P.:

In 37 CFR 1.822(e) the procedures for presenting and numbering hybrid and gapped sequences are set forth. A sequence that is made up of one or more non-contiguous segments of a larger sequence or segments from different sequences, *i.e.*, a hybrid sequence, shall be presented as a separate sequence. A "gap" for the purpose of this section is not intended to embrace a gap or gaps that is/are introduced into the presentation of otherwise continuous sequence information in, *e.g.*, a drawing figure, to show alignments or similarities with other sequences. The "gaps" referred to in this section are gaps representing unknown or undisclosed regions in a sequence between regions that are known or disclosed.

Thus, Applicants have no means by which the gaps in the sequence depicting the alignment sequence can be presented and respectfully request that the Examiner relax absolute conformance with the Sequence Rules (only with respect to the sequences depicting the alignment sequences presented within the figures). Applicants respectfully assert that no new matter has been added by

any of the amendments and submit that the Brief Description of the Figures section has been amended to identify the sequence identifiers in Figures 1, 3, 5, 7, 8, 10, 11, and 13. The sequences shown in replacement Figures 4 and 6 of the subject specification have also been designated with a sequence identifier number. A Submission of Sequence Listing Under §1.821, including a replacement sequence listing on paper and a computer readable format is attached. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 96-103 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The Office Action indicates that claims 96-103 are indefinite because the claims lack an essential step in the method of treating viral or acute liver disease. Applicants respectfully asserts that the claims do not omit essential steps. However, by this Amendment Applicants have amended the claims to clearly indicate that the pharmaceutical composition is administered in an amount effective to treat a viral or acute liver disease. Applicants respectfully assert that the claims as filed are definite; however, in the event that the Examiner still believes that further revision of the method claims is required, the courtesy of a teleconference to discuss the claims is respectfully requested. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 75, 78, 79, 81, 82, 85, 86, 88, 89, 92, 93 and 95 are rejected under 35 U.S.C. § 102(a) or 102(e) as obvious over Hu *et al.* (WO 02/066624). The Office Action indicates that Hu *et al.* teach identification and characterization of a nucleotide (SEQ ID NO:1) that encodes a novel human protein (NHP) having the amino acid sequence of SEQ ID NO:2, which shares structural similarity with metalloproteases and having protease activity and has 95.7% sequence identity to the amino acid sequence of SEQ ID NO:34. The Office Action further states that Hu *et al.* teach labeled NHP fusion proteins such as alkaline phosphatase-NHP, NHP-alkaline phosphatase or NHP-IgFc fusion proteins. The Office Action concludes that it would have been obvious to the person of skill in the art that a pharmaceutical or immunogenic composition comprising NHP, NHP-IgFc fusion proteins, or NHP antibody would be prepared. Applicants respectfully assert that the Hu *et al.* reference does not anticipate the claimed invention as the cited reference fails to teach a polypeptide having at least 97% identity to the claimed polypeptide. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(a) or (e) is respectfully requested.

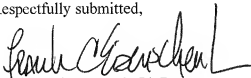
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Replacement sequence listing (pages 1-39)
Replacement figures 4 and 6
Submission of Sequence Listing and Statement